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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,020	10/02/2003	Tetsuya Isobe	KAS-192	6446
7590 MATTINGLY, STANGER & MALUR, P.C. Suite 370 1800 Diagonal Road Alexandria, VA 22314			EXAMINER TURK, NEIL N	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 09/11/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/676,020

Applicant(s)

ISOBE ET AL.

Examiner

NEIL TURK

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 31st, 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/2/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on July 31st, 2008. Claims 16-21 have been newly added and are pending. Claims 1-15 have been cancelled. Any objection/rejection not repeated herein has been withdrawn by The Office.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 31st, 2008 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the reagent bottle having a plurality of openings closed by puncturable seals of **claim 19** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: there are no analysis elements claimed. Claims 16-21 are drawn to an automatic analyzer, however the body of independent claim 16 and dependent claims 17-21 do not recite any analysis elements that would provide for an automatic analyzer. .

Claim 19 recites the limitation "said reagent bottle". There is insufficient antecedent basis for this limitation in the claim. Examiner asserts that Applicant intends to recite "said at least one reagent bottle".

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation, "...wherein said reagent bottle has a plurality of openings closed by puncturable seals..." is unclear. The relationship of the openings to the puncturable seals is unclear. Does Applicant intend to recite that each opening has a corresponding seal, or does Applicant intend to recite that each opening has more than one corresponding seal?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Long (5,200,151) in view of Court et al. (5,863,752), hereafter Court, and Lopez et al. (4,752,292), hereafter Lopez, and Homberg et al. (5,792,424), hereafter Homberg.

Long discloses a fluid dispensing system having a pipette assembly with a preset tip locator (abstract). Long discloses assay modules 22 (reaction cells) with reaction zones within the modules (lines 41-67, col. 3). Long discloses a movable table 68 (container for seal piercing tool) which holds pipette tips 70 (seal piercing tool) that are to be affixed to the stem 72 (nozzle) of the pipette 40, and the table 68 also holds reservoirs 66 (reagent bottles) for holding reagents. Long discloses a vertical drive 78 of an X-Y-Z transport mechanism 64 with the pipettes, where the vertical drive 78 (for attaching the piercing tool to the nozzle) allows the pipette to be driven down to affix the pipette tip to the stem (lines 41-67, col. 4, figs. 1&2). Long further discloses that the transport is operative in the process of affixing a tip 70 to the stem 72 of a pipette 40

and in the detachment of the tip from the stem. Long discloses an extractor 116 for removing the pipette tip 70 and depositing the tips into bin 120 (lines 1-67, col. 6, fig. 2). With regards to the container being functionally recited in claim 16 as being for holding the piercing tool before attachment and for holding the piercing tool after the tool is released, Examiner asserts that such a recitation is drawn to a capability of the container and is defined functionally. Examiner asserts that as the claims are drawn to an apparatus, the claim recitation must distinguish over the prior art of Long in terms of structure rather than in terms of function. Thereby, Examiner asserts that Long discloses a container, which is the positively claimed structural element, and thereby such a container is *capable* of holding the piercing tool at any time in the operation of attaching/detaching the piercing tool. Further, with regards to claims 17-20 the claim recitations to the reagent sampling mechanisms are functionally described and do not further limit the structure of the device; the transport mechanisms of Long are said to be capable of such functionalities, as the requisite structure of a sampling mechanism is disclosed by Long.

With regard to claim 16, Long does not specifically disclose at least one reagent bottle having an opening closed by a puncturable seal. Further, Long does not disclose that the piercing tool comprises a lever locking the piercing tool on the nozzle.

Court discloses a flexible diaphragm, or septum-sealed bottles for containing reagent (abstract; lines 37-39, col. 1; line 48, col. 2 – line 7, col. 3).

Lopez discloses a medical connector in which a piercing tool 92 (the cap is capable of piercing) has a latch locking mechanism 90, with a spring 130 for biasing the

lever to a closed position with respect to the nozzle 91, where it engages slots 102 and 103a (port 91 and its structure act as a nozzle) (lines 9-32, col. 8; line 51, col. 9 - line 15, col. 10; figs. 7-10a).

It would have been obvious to modify Long to include septum-sealed reservoirs (bottles) for the reagent such as taught by Court in order to provide puncturable seals accessible by the nozzle tips of Long while providing protection from contamination and evaporation to the reagent within the reservoirs while not in use. It would have been obvious to modify Long to include a lever mounted on the piercing tool such as taught by Lopez in order to provide structure to the piercing tool that would allow for reliably and releasably securing the piercing tool to the nozzle. Further, with regard to **claim 19**, it would have been an obvious modification to multiply the parts of Court to include a reagent bottle with a plurality of openings closed by a plurality of seals so as to provide a reagent bottle that is accessible at a plurality of discrete points and closed by a plurality of seals in order to provide several access points and added sealing to avoid contamination and unwanted exposure of the bottle.

With regards to claim 18, Long does not disclose a separate and additional disk for holding the reagent bottles and does not disclose that they are arranged around a circumference of the disk. Long does, however, disclose a movable table 68 in which reagent reservoirs 66 are arranged. It would have been an obvious design choice to place the reagent reservoirs 66 on a separate table from the tips 70, in the form of a disk, so as to allow for a design in which the two sets of elements are separated to avoid incidental contact and unwanted cross-talk and contamination of the elements;

further, modification to a disk shape is an obvious design modification of shape in order to optimally fit the space of placement or to provide the right aesthetic for marketing purposes.

With regard to claim 21, Long does not disclose that the piercing tool has a slidable guide.

Homberg discloses a slidable guide 60 at the lower end that is urged toward downward to stop 46 by a spacing spring 70 (lines 10-49, col. 15, fig. 11).

It would have been obvious to modify Long to include a slidable guide such as taught by Homberg in order to provide an adjustable guide for selectively exerting a force to apply the piercing tool to the intended position.

Response to Arguments

Applicant's arguments with respect to claims 9-15 have been considered but are moot as claims 9-15 have been cancelled. Further, newly added claims 16-21 are now rejected in view of the new ground(s) of rejection as discussed above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797